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**INDEPENDENT REGULATORY REVIEW COMMISSION
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November 5, 2003

Honorable Calvin B. Johnson, M.D., Secretary
Department of Health
802 Health and Welfare Building
Harrisburg, PA 17108

Re: Regulation #10-174 (IRRC #2355)
Department of Health
Out-of-Hospital Do-Not-Resuscitate Orders

Dear Secretary Johnson:

Enclosed are the Commission's comments for consideration when you prepare the final version of this regulation. These comments are not a formal approval or disapproval of the regulation. However, they specify the regulatory review criteria that have not been met.

The comments will be available on our website at www.irrc.state.pa.us. If you would like to discuss them, please contact my office at 783-5417.

Sincerely,

Robert E. Nyce
Executive Director

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Enclosure

cc: Honorable Harold F. Mowery, Jr., Chairman, Senate Public Health and Welfare Committee
Honorable Vincent J. Hughes, Minority Chairman, Senate Public Health and Welfare Committee
Honorable George T. Kenney, Jr., Majority Chairman, House Health and Human Services Committee
Honorable Frank L. Oliver, Democratic Chairman, House Health and Human Services Committee

Comments of the Independent Regulatory Review Commission

on

Department of Health Regulation No. 10-174

Out-of-Hospital Do-Not-Resuscitate Orders

November 5, 2003

We submit for your consideration the following comments that include references to the criteria in the Regulatory Review Act (71 P.S. § 745.5b) which have not been met. The Department of Health (Department) must respond to these comments when it submits the final-form regulation. The public comment period for this regulation closed on October 6, 2003. If the final-form regulation is not delivered within two years of the close of the public comment period, the regulation will be deemed withdrawn.

1. Section 1005.3. Right to enter, inspect and obtain records. - Clarity.

The Preamble states the Department's intention to use a reference to Subpart A. However, this reference is not shown in Section 1005.3. Was it the Department's intention to publish the subsections under Section 1005.3?

2. Section 1051.13. Person who loses authority to function as a surrogate. - Reasonableness.

There are three questions related to the change of surrogates. First, does an out-of-hospital do-not-resuscitate (DNR) order remain valid if it was established by a surrogate who is subsequently replaced? If so, how could the new surrogate become aware of an existing out-of-hospital DNR order?

Second, this section places responsibilities on former surrogates. However, there is no parallel provision that places responsibilities on the current surrogate. Should similar responsibilities, such as contacting the attending physician, be placed on the current surrogate?

Finally, Subsections (b) and (c) require a former surrogate to help the physician locate "the patient **or** the patient's current surrogate." (Emphasis added.) If the patient is unable to communicate, it may be difficult for the physician to locate the current surrogate. Should the word "or" be replaced by "and"?

3. Section 1051.23. Disclosures to patient requesting out-of-hospital DNR order and Section 1051.24. Disclosures to surrogate requesting out-of-hospital DNR order. - Protection of the public health, safety and welfare.

We have three questions. First, why don't Sections 1051.23(9) and 1051.24(5) mandate a physician to contact the patient or surrogate to rescind the out-of-hospital DNR order if the physician discovers the diagnosis of the terminal condition was in error? If the premise for the out-of-hospital DNR order is in error, an "attempt" to notify the patient or surrogate may not sufficiently protect the patient.

Second, why don't Sections 1051.23(6) and 1051.24(4) require notice to the physician if the patient or surrogate revokes the out-of-hospital DNR order without the physician's approval or knowledge? Subsequent notice to the physician should be required, particularly if a surrogate revoked the order.

Finally, to what other procedures is the Department referring in Sections 1051.23(5)? The Department should specify what these procedures are by cross-referencing them, or delete the phrase "in accordance with other procedures" from this subsection.

4. Section 1051.26. Physician refusal to issue an out-of-hospital DNR order. - Reasonableness; Clarity.

We have two questions on Paragraph (2). First, a physician who is not willing to issue an out-of-hospital DNR order is required to "offer to assist the patient or surrogate to secure the services of another physician who is willing to issue an out-of-hospital DNR order." As written, this requirement presumes that the attending physician knows what diagnosis and conclusion another physician will make. Why is the phrase "who is willing to issue an out-of-hospital DNR order" appropriate?

Second, to what degree is a physician required to assist a patient in obtaining an out-of-hospital DNR order from another physician? Will a referral be sufficient?

5. Section 1051.29. Duty to contact patient or surrogate. - Protection of the public health, safety and welfare.

This section requires a physician to "make a good faith effort" to contact the patient to rescind the out-of-hospital DNR order if the physician discovers the diagnosis of the terminal condition or permanent unconsciousness was in error. If the premise for the out-of-hospital DNR order is in error, shouldn't notification of the patient or surrogate be mandatory?

6. Section 1051.30. Physician destruction of out-of-hospital DNR order, bracelet or necklace.

The preamble states that a physician must have confirmation of the destruction of the out-of-hospital DNR order from a "reliable person" if they do not destroy the order themselves. Subsection (b) of this section does not include this language. The phrase "reliable person" should be added to Subsection (b) and defined in Section 1051.2.

7. Section 1051.51. Implementation of out-of-hospital DNR order. - Reasonableness; Clarity.

Subsection (a) of this section states, "...the EMS provider shall implement the out-of-hospital DNR order only if it contains original signatures." We have two concerns.

First, why are "original signatures" required? Also, how can the EMS provider readily determine if the out-of-hospital DNR order contains original signatures?

Second, commentators have suggested that prehospital practitioners should be able to accept an unaltered copy of the original out-of-hospital DNR order. Is there any reason an unaltered copy wouldn't be acceptable?